Biotech Daily

Tuesday July 13, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ANTISENSE UP 25%; SUNSHINE DOWN 9%**

*** AVEXA: DR JONATHAN COATES CEO; JET SOEDIRDJA DIRECTOR; REVIEW**

*** TISSUE THERAPIES WOUND CARE TRIAL 'EXTRAORDINARY RESULTS'**

*** LIVING CELL NZ TRIAL: PIG CELLS REDUCE INSULIN DEPENDENCE**

*** CLINUVEL PHASE III TRIAL: 'SCENESSE REDUCES SUNLIGHT PAIN'**

*** ANTISENSE WORKING ON MULTIPLE LICENCING DEALS**

*** FLUOROTECHNICS REVENUE UP, BELOW EXPECTATIONS**

*** CAPITAL GROUP CLIENTS REDUCE 1% IN COCHLEAR**

*** KFT, PFM CORNERSTONE INCREASE IN CATHRX**

MARKET REPORT

The Australian stock market fell 0.67 percent on Tuesday July 13, 2010 with the S&P ASX 200 down 29.6 points to 4380.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and seven were untraded. All three Big Caps were up.

Antisense was best, up 0.4 cents or 25 percent to two cents with 31.1 million shares traded, followed by Bionomics up two cents or 7.1 percent to 30 cents with 24,131 shares traded.

Benitec climbed 6.7 percent; QRX was up five percent; Phosphagenics was up 4.3 percent; Novogen and Prana were up more than three percent; Cochlear, Genetic Technologies and Tissue Therapies rose more than two percent; with Biota and CSL up more than one percent.

Sunshine Heart led the falls, down 0.3 cents or 8.6 percent to 3.2 cents with 725,382 shares traded, followed by Prima down eight percent to 11.5 cents with 6.8 million shares traded.

Viralytics lost 7.3 percent; LBT fell 4.6 percent; Chemgenex and Psivida were down more than three percent; Alchemia shed 2.6 percent; with Pharmaxis, Starpharma and Virax down one percent or more.

AVEXA

Avexa has appointed Dr Jonathan Coates as interim chief executive officer and chief scientific officer, with Jet Soedirdja appointed as a non-executive director.

Dr Coates told Biotech Daily that the company and the board of directors "are committed to a fully independent review".

Dr Coates is the inventor of apricitabine or ATC for HIV, which was shown in a phase III trial not to be statistically significantly superior to his earlier invention 3TC.

The then Avexa chief scientist officer, Dr Coates resigned from Avexa at the same time as then chief executive officer Dr Julian Chick and former head of clinical development Dr Susan Cox when chairman Nathan Drona told the ASX that the board had unanimously agree to drop the ATC program (BD: May 10, 2010).

Mr Drona and director Uri Ratner were removed from the Avexa board last week and replaced with Steven Crowley and Bruce Hewett, with former director Joe Baini, rejoining the board (BD: May 26; Jul 6, 2010).

While Avexa has been able to demonstrate that apricitabine has efficacy and that of the 36 patients who successfully completed the phase II study, "94 percent [34 patients] maintained undetectable viral loads up to week 144", the 24-week data from its phase III HIV trial showed a non-significant positive clinical benefit for apricitabine compared to the standard of care, 3TC (BD: Feb 4, 5 and 15, 2010).

On May 10, 2010, Avexa said detailed results from the phase III trial were provided to interested parties to secure a licencing transaction but on May 6, 2010, the last party involved in the process said it did not intend to submit a term sheet.

Today Dr Coates told Biotech Daily that his job as acting chief executive officer was "to stand back and look at all the programs as well as ATC".

Biotech Daily asked Dr Coates what options were available to Avexa for ATC other than finding a major pharmaceutical company prepared to put up tens of millions of dollars for a new phase III trial or - given the requests by AIDS groups (BD: Jun 18, 2010) - providing it at a nominal fee to charitable organizations.

"It is on the table as an option," Dr Coates said. "My job is to act as a resource, but it has to be a decision for the company. All options are open."

"I think there is a way forward for ATC if we can find a trial design palatable to the regulatory authorities and a partner, be it large to mid-size pharma," Dr Coates said.

"In recent times the FDA has allowed drugs to be approved having met their clinical endpoints in highly drug experienced and resistant patients," Dr Coates said.

"In such a changed trial design the difference between ATC and 3TC would be more obvious," Dr Coates said.

Biotech Daily has been told that the large number of background drugs involved with earlier stage patients partly masked the difference between ATC and 3TC.

Avexa chairman Joe Baini said in Avexa's media release that he was "delighted to welcome Jonathan back to Avexa".

"We are fortunate to have a person with such strong experience in the development of drugs to target infectious diseases and HIV, as well as familiarity with all of Avexa's programs, to lead the company while we conduct the independent review and progress discussion with regulatory authorities in relation to the potential for its HIV drug candidate, apricitabine," Mr Baini said.

Avexa said that Jet Soedirdja was an experienced company director and had been a director of Mosaic Oil and the Indonesian based investment group PT Dragon Capital Management as well as an investment advisor at Bell Potter Securities and an advisor at RBS Morgans (formerly ABN Amro Morgans) and Credit Suisse First Boston.

Avexa fell 0.1 cents or 2.9 percent to 3.3 cents with 1.2 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says the first four patients in its New Zealand phase II clinical trial of Diabecell for diabetes have reduced their episodes of low blood glucose.

Living Cell said four patients received 10,000 islet equivalents/kg implants of encapsulated pig islet of Langerhans cells and four more patients have received 15,000 IEQ/kg each.

The company said the first four patients all showed a reduction or elimination of episodes of life-threatening low blood-glucose levels without remarkable adverse events attributable to the treatment, two patients had been followed-up for 24 weeks and two for 12 weeks.

The company said that by 12 weeks, the severity score of hypoglycaemic episodes in the first four patients was reduced by a mean of 67 percent with the numeric score of 83 reduced to 28 and the number of hypoglycaemic episodes was reduced by 44 percent or 30 episodes reduced to 17 eposides.

In three patients with hypoglycaemic unawareness, the number of such episodes was reduced by 90 percent from 19 events to two events.

At 24 weeks one patient experienced only one further episode of hypoglycaemic unawareness while the other patient had no further attacks.

In the first four patients, the insulin dose reduction ranged from six percent to 25 percent at 12 to 24 weeks.

Living Cell said blood glucose control as reflected by HbA1c and 72-hour continuous glucose monitoring showed improvement and details of HbA1c and continuous blood glucose monitoring were blinded to the clinical team which served as independent trial officiators and would be unblinded after one year follow-up.

Living Cell said four more patients received a higher dose of 15,000 IEQ/kg with no significant adverse events attributed to treatment and the follow-up period was underway.

Living Cell chief executive officer Dr Paul Tan said the company was planning to expand clinical trials to obtain the necessary data for the treatment to be approved.

Living Cell said the New Zealand trial's interim results were due in October 2010 and final unblinded results after one year follow-up.

Living Cell was unchanged at 20 cents.

TISSUE THERAPIES

Tissue Therapies says its Australian clinical trial of Vitrogro for chronic venous ulcers has shown "extraordinary" positive results.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that of the 22 patients treated so far, four had complete healing and in some cases with years of failed treatments and it was extraordinary to make such a difference.

Dr Mercer said there was very little Vitrogro left from the trial but the company had completed commercial scale good manufacturing practice production of Vitrogro for a European trial due to begin "shortly" and be completed this year.

Dr Mercer said the Australian clinical trial was under the supervision of Prof Michael Stacey who would have sufficient Vitrogro for "one or two more patients".

In a media release to the ASX Dr Mercer said 22 chronic venous ulcer patients had been treated with Vitrogro for 24 days with complete healing of four ulcers and an average reduction of ulcer area of 40 percent ($p < 0.0001$).

Tissue Therapies said the average age of patients was 68 years and the average duration of the venous ulcer prior to Vitrogro treatment was 13 months.

The company said the results were in addition to the "exceptional results" achieved in the Canadian trial of 10 patients (BD: Nov 18, 2009).

Tissue Therapies was up half a cent or 2.7 percent to 19 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says its phase III trial showed that Scenesse reduced and prevented painful phototoxic reactions experienced by patients with erythropoietic protoporphyria.

Clinuvel's head of global network and communications Lachlan Hay told Biotech Daily that the 12 month European and Australian 91 patient cross-over study of Scenesse or afamelanotide (formerly known as CUV1647) demonstrated that average pain severity experienced by the total number of patients, the assessment of all individual daily pain scores, was significantly lower in patients receiving Sceneese compared to those receiving placebo ($p = 0.0017$).

In data posted on its website, Clinuvel said the primary endpoints were the mean number of phototoxic reactions and mean severity score for phototoxic reactions when comparing active drug to placebo as measured by pain scales and clinical observation.

The secondary endpoints included changes in melanin density measured by spectrophotometry, amount of sunlight exposure, change in quality of life and the mean time taken to provoke symptoms.

In the data posted on its website but not released to the ASX, the company said patients were divided into two groups and in a multiple crossover design received 16mg afamelanotide or placebo implants once every two months for a total of six implants administered subcutaneously over a 12 months period.

See: http://www.clinuvel.com/resources/cmsfiles/pdf/20100713CUV017Results.pdf.

While there was no direct comparison of the effects of the active compared to placebo in the data published on its website, Clinuvel said the complete results would be presented at the 19th Congress of the European Association for Dermatology and Venereology in Gothenburg, Sweden in October, 2010.

The company said there was a significant difference in pain scores ($p = 0.0023$) and a reduction in the average patient's daily severity score ($p = 0.1654$) along with increases in average melanin density and quality of life.

Clinuvel said there were eight serious adverse events, of which four were with the placebo recipients.

Most adverse events were mild or moderate in severity, with headache, nausea, flushing and gastrointestinal events reported most often, the company said.

Clinuvel chief executive officer Dr Philippe Wolgen said the "long-awaited results have taken us closer to our ultimate commercial objectives in the interests of both the patients as well as investors".

"In EPP we are treating an orphan disease for which no comparable therapy can be accessed, as such, the demonstration of both short and long-term safety data, is the single-most important parameter in the regulatory review process," Dr Wolgen said.

"This statistical outcome on safety and treatment effect support in presenting efficacy data to the regulatory authorities, whereby it is relevant to our filing that no other group has ever conducted large-scale therapeutic trials in this disease or has attempted to measure the effects of light on skin," Dr Wolgen said.

Clinuvel said erythropoietic protoporphyria was characterized by pain and that patients' skin burned, blistered and scarred when exposed to normal levels of light and sun.

The company said it was estimated that 10,000 individuals worldwide are afflicted with EPP.

Clinuvel said the study showed that Scenesse treatment significantly reduced the average daily pain severity scores experienced by EPP patients compared to placebo and treatment with Scenesse allowed patients to expose their skin to sunlight and spend more time outdoors; previously unheard of in EPP.

Clinuvel was unchanged at 24.5 cents.

ANTISENSE THERAPEUTICS

Antisense says it is making “significant progress” on licencing opportunities for ATL1102 for multiple sclerosis and asthma as well as ATL1101 for cancer.

Antisense said it had supplied ATL1101 drug product to a specialist oncology company for tests on their in-house animal cancer models with a view to licencing the drug.

The company said that previous animal studies in collaboration with Vancouver Prostate Cancer Centre researcher Prof Martin Gleave ATL1101 demonstrated its effectiveness in suppressing human prostate cancer tumor growth.

Antisense said that ATL1101 targeted the insulin-like growth factor-1 receptor (IGF-IR) which was a high interest therapeutic target in oncology and drugs targeting IGF-IR were being developed by a number of pharmaceutical companies for a variety of cancers.

The company said that ATL1101 was the only gene-silencing or RNA-targeting drug known to be in development for that target.

Antisense said it was “actively seeking a partner” to continue the development of ATL1102 for multiple sclerosis and had “received requests from major pharmaceutical companies for information on ATL1102 so that they can evaluate their potential interest in licencing this compound”.

Antisense said ATL1102 was shown to be highly effective in reducing multiple sclerosis lesions in a phase II clinical trial.

The compound was licenced to Israel’s Teva Pharamceuticals in 2008 in a potential $US100 million deal, paying an upfront fee of $US2 million (BD: Feb 11, 2008) but earlier this year handed the drug back to Antisense (BD: March 24, 2010).

The company said it was “in the final stages of the handover process relating to the termination of the licence agreement with Teva” with all the rights, patents and data having been returned and the data generated by Teva including the reports from the chronic toxicology studies expected to be handed to Antisense, providing “a complete and comprehensive package of data and [intellectual property] rights” for potential licencing.

Antisense said it had also singed a confidentiality agreement with a drug development company interested in the inhaled application of ATL1102 for asthma.

Antisense said it had conducted animal studies on ATL1102 for asthma and there was growing interest in the inhaled or aerosol use of antisense drugs for the treatment of asthma given the positive results demonstrated in clinical trials.

Antisense said its growth hormone receptor targeting drug ATL1103 was “an ideal candidate to further develop and move into human clinical trials which would potentially add significant value to any future commercialization deal”.

The company said the first in-human trial of ATL1103 aimed to confirm both the safety of the drug and its effectiveness in reducing IGF-I levels in the blood which is an easy-to-measure and generally accepted clinical endpoint for the treatment of the growth disorder acromegaly.

Antisense said that IGF-I reduction mighty also have a role in the treatment of certain forms of cancer and in diabetes-associated diseases such as diabetic retinopathy and nephropathy.

The company said its US collaboration partner Isis Pharmaceuticals had completed manufacture of supplies of ATL1103 for the clinical trial.

Antisense said it had reported the completion of pre-clinical toxicology studies and expected to submit an application for the human clinical trial in the second half of 2010.

Antisense was up 0.4 cents or 25 percent to two cents with 31.1 million shares traded.

FLUOROTECHNICS

Fluorotechnics says revenue for the year ended June 30, 2010 was $3.5 million compared to $3.2 million in the year to June 30, 2090.
Fluorotechnics said the revenue was “below expectations as our major markets of Europe and the US continue to be affected by the global financial crisis” which continued to impact on the buying decisions of potential customers.
The company said sales of its HPE Flat Top system were building but at a rate below expectations.
Fluorotechnics was untraded at 10 cents.

COCHLEAR

The US based Capital Group Companies has reduced its substantial shareholding in Cochlear from 6,786,361 shares (12.00%) to 6,193,350 shares (10.95%).
Capital Group had been increasing its holding since November 3, 2008 when it had 8.80 percent of the company and last increased its holding in September 2009.
Capital Group said it did not own shares in Cochlear but held them on account for Capital Research and Management Company.
The 593,011 shares were sold at an average price of $71.25.
Cochlear climbed $1.72 or 2.4 percent to $72.72.

CATHRX

KFT Investments directly and PFM Cornerstone indirectly increased their substantial holding in Cathrx.
KFT said it had an interest in PFM which separately has been diluted in the recent 16 cents a share rights issue.
PFM’s 24,341,610 shares were diluted from 22.174 percent to 17.048 percent.
KFT said it had increased its holding in Cathrx from 8,372,689 shares (19.65%) to 31,591,610 shares (22.126%).
KFT said it acquired the 23,220,021 shares for $4,411,982 or an average price of 19 cents a share.
Cathrx was unchanged at 25 cents.